

REMARKS

After entry of the present Amendment, claims 1-9, 11-13, 15 and 17-53 are pending in the Application. Claims 19-22, 33-47 and 50-53 stand withdrawn. Claims 10, 14 and 16 were cancelled, claims 1-9, 11-13, 15, 28, 29 and 49 were amended. No new matter is introduced. Applicants submit that the specification supports the amended claims.

In particular, support for the recitation of “reproductive cell” in claims 1-9 can be found in the specification at least at page 2, paragraph 11. The remaining amendments correct typographical errors or claim dependencies, or are supported by the original claims as filed.

The pending claims stand variously rejected. Each rejection is respectfully traversed as discussed below. Applicants respectfully submit that the pending claims are in condition for allowance and earnestly solicit notification to that effect.

Claim Objections

Claims 28 and 49 were objected to for missing punctuation. These typographical errors have been corrected herein. Therefore, Applicants respectfully request withdrawal of the objections.

Rejection under 35 U.S.C. § 102(b)

In the Office Action, claims 1-12, 14-16, 18, 23, 24, 26, 29, 32 and 48 are rejected as anticipated under 35 U.S.C. § 102(b) by U.S. Patent No. 6,150,163 in light of evidence provided by an ATCC catalogue. Claims 1-11, 18, 23, 33 and 48 are rejected as anticipated under 35 U.S.C. § 102(b) by Naz et al. in light of evidence provided by the ATCC catalogue. Claims 1-9, 14, 15, 32 and 48 are rejected as anticipated under 35 U.S.C. § 102(b) by Lackey et al.

Claims 10, 14 and 16 have been cancelled and claim 33 has been withdrawn, thereby mooted the rejections with respect to these claims. Inasmuch as the rejections may be applied to the presently pending amended claims, Applicants respectfully traverse.

In order to anticipate, a reference must teach every aspect of the invention either explicitly or impliedly. MPEP 2131. Applicants respectfully assert that none of U.S. Patent No. 6,150,163, Naz et. al. or Lackey et al. explicitly or impliedly disclose every aspect of the presently claimed invention as required by this standard.

U.S. Patent No. 6,150,163 discloses a serum-free, defined cell culture media useful in culturing fibroblasts, especially chondrocytes (see, e.g., Abstract, claim 11). Importantly, no other cell type is described or even mentioned in the reference. The defined media described in

the '163 patent includes a supplement mixture, a component mixture, a vitamin mixture, an inorganic salt mixture and an amino acid mixture (Col. 2, lines 57-61).

Naz et al. discloses that TGF β -1 enhances expression of a 50 kDa protein related to 2-5(A)synthetase in human sperm cells (Abstract). No mention whatsoever is made of any insulin-like growth factor.

Lackey et al. disclose the effects of insulin-like growth factors on bovine sperm motility (Abstract). No mention whatsoever is made of any transforming growth factor.

In contrast, amended independent claim 1 requires a composition comprising a reproductive cell and a medium, wherein the medium comprises at least one insulin-like growth factor and at least one transforming growth factor. Independent claim 49 requires a composition comprising a sperm cell medium for porcine sperm cells, wherein the medium comprises TGF β -1, TGF β -2 and IGF-1. None of the cited references teach, either explicitly or impliedly, a composition comprising all of these required elements. Accordingly, independent claims 1 and 49 are allowable over each of the '163 patent, Naz et al. and Lackey et al. Claims 2-9, 11, 12, 15, 18, 23, 24, 26, 29, 32 and 48, which depend from claim 1, are also therefore allowable over each of the references, as well. Notification to that effect is earnestly solicited.

Rejections under 35 U.S.C. § 103

In the Office Action, claims 1-18, 23-32, 48 and 49 are rejected under 35 U.S.C. § 103 as obvious over U.S. Patent No. 6,150,163. Claims 1-18, 23-32, 48 and 49 are rejected as obvious over Naz et al. and Lackey et al. taken with the ATCC Catalogue in view of U.S. Patent No. 6,140,121, U.S. Patent No. 6,150,163, and Nocera et al.

Claims 10, 14 and 16 have been cancelled, thereby mooted the rejections with respect to these claims. Inasmuch as the rejections may be applied to the presently pending amended claims, Applicants respectfully traverse.

To establish *prima facie* obviousness: 1) there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify or combine the teachings; 2) there must be a reasonable expectation of success; and 3) the references must teach or suggest all of the claimed limitations. MPEP 2142. Moreover, the teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. In re Vaack, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Applicants respectfully assert that the Office Action does not set forth a *prima facie* case of obviousness with regard to the outstanding rejections.

U.S. Patent No. 6,150,163

With respect to the rejection based on U.S. Patent No. 6,150,163, it is respectfully asserted that no motivation is provided therein to modify the teachings of the reference to arrive at the presently claimed invention. Further, the '163 Patent does not provide any reasonable expectation of success vis-à-vis the presently claimed invention. Finally, Applicants assert that all of the claimed limitations are not taught or suggested.

The Office Action states that "it is within the purview of the ordinary skill practitioner to adjust concentrations of particular growth factors and/or other ingredients with regard to a particular type of cells or a type of animals for the expected benefit in maximizing animal cell viability and/or optimizing animal cell survival, grow, proliferation, differentiation and/or preservation." However, the only "expected benefit" taught by the '163 Patent is enhancing the differentiation of chondrocytes while avoiding the problems inherent in the use of serum. Col. 2, lines 57-63. The reference does not teach that the media taught therein is useful for culturing any cell type from any animal, much less that cell viability, survival, growth and/or preservation can be maximized. Indeed, the proposition that a given media would be suitable for any and all animal cells for any and all purposes is unrealistic at best. In particular, it is well known that different cell types have different nutritional and growth requirements. Differences in pH, for example, can have a profound effect on cell survival. Thus, the '163 Patent provides no motivation to modify its teachings to provide a media suitable for reproductive cells.

Moreover, chondrocytes, which are a type of fibroblast, differ in many respects from reproductive cells. Fibroblasts are diploid cells whereas reproductive cells are haploid. Fibroblasts proliferate whereas reproductive cells are preprogrammed for cell death. Importantly, reproductive cells are notoriously sensitive to media components, whereas fibroblasts are relatively hardy. Thus, one of skill in the art would not expect to successfully prolong viability of reproductive cells using a media specifically formulated to promote chondrocyte differentiation.

The '163 Patent also does not teach or suggest all the claimed elements. The pending amended claims each require at least a reproductive cell. As mentioned, the '163 Patent does not remotely teach or suggest a composition comprising any reproductive cell.

Naz et al. and Lackey et al. taken with the ATCC Catalogue in view of U.S. Patent No. 6,140,121, U.S. Patent No. 6,150,163, and Nocera et al.

With respect to the rejection based on Naz et al. and Lackey et al. taken with the ATCC Catalogue in view of U.S. Patent No. 6,140,121, U.S. Patent No. 6,150,163, and Nocera et al., it is respectfully asserted that no motivation is provided in any of the cited references to modify or combine the disclosures to arrive at the presently claimed invention. Further, the cited references do not provide any reasonable expectation of success vis-à-vis the presently claimed invention.

The Examiner has clearly used impermissible hindsight reconstruction to arrive at the presently claimed invention using the cited references. “The mere fact that the references can be combined or modified does not make the resultant combination obvious unless the prior art also suggests the desirability of the combination.” MPEP 2143.01, citing *In re Mills*, 916 F.2d 680 (Fed. Cir. 1990).

Naz et al. teach that TGF- β 1 enhances expression of a 50 kDa protein in human sperm cells (Abstract). The reference also teaches that the increase has no effect on sperm motility (Abstract) or function (page 161, col. 1). Naz et al. certainly provide no motivation to utilize any TGF as a media component and certainly do not suggest combining it with other components to achieve prolonged reproductive cell survival. Similarly, while Lackey et al. teach that IGFs have an effect on sperm motility and are found in human seminal plasma, there is no motivation to use IGFs as a media component, much less to use them in combination with TGFs in reproductive cell media.

The secondary references fail to cure these deficiencies. As argued above and for the same reasons, the ‘163 Patent, directed to media for enhancing differentiation of chondrocytes, is not properly applied to the presently claimed invention, directed to compositions comprising a reproductive cell and media therefor. Nocera et al. and the ‘121 Patent also provide no suggestion to combine the separately taught elements of the present invention.

The citation in the Office Action of *In re Pinten*, *In re Susi* and *In re Crockett* is inappropriate in the present situation. While it is true that it is obvious to combine two or more ingredients, each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition which is useful for the same purpose, that is not the instant case. None of the references cited by the examiner teach that any of the claimed ingredients are useful for *any* purpose, much less the same purpose. Certainly none of the references suggest using any of the claimed ingredients as reproductive cell media.

Moreover, even assuming *arguendo* that the necessary motivation is taught by the references, none of the references indicate that there would be a reasonable expectation of

success. Merely teaching that a particular claimed element is a component of human seminal plasma, e.g., Nocera and Lackey, is not sufficient to teach that use of these elements in media would successfully prolong viability. No cited reference, or even a combination of the cited references, provides one of skill in the art with any reason to believe that the claimed composition would successfully achieve the results taught in the instant specification.


Summary

In summary, for the above-mentioned reasons, Applicants respectfully request withdrawal of the rejections under 35 U.S.C. §103 over the cited references, as the Office Action fails to set forth a *prima facie* case of obviousness with respect to either rejection.

CONCLUSION

In view of the foregoing, reconsideration and allowance of claims 1-9, 11-13, 15, 17, 18, 23-32, 48 and 49 is respectfully requested. The Examiner is strongly encouraged to contact the undersigned by telephone at the Examiner's convenience should any issues remain with respect to the Application.

Respectfully submitted,

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